

Protecting and Improving the Health of Iowans

Kim Reynolds, Governor

Adam Gregg, Lt. Governor

Kelly Garcia, Interim Director

COVID-19 Vaccine Information Brief

January 31, 2022

Changes to the document from the previous version are highlighted in yellow.

U.S. FDA Fully Approves Moderna's COVID-19 Vaccine for Those 18 Years and Older

On Monday, January 31, 2022 the FDA approved a second COVID-19 vaccine. The vaccine has been known as the Moderna COVID-19 Vaccine, and will be marketed as Spikevax for the prevention of COVID-19 in individuals 18 years of age and older. Spikevax has the same formulation as the EUA Moderna COVID-19 Vaccine and is administered as a primary series of two doses, one month apart.

 Spikevax can be used interchangeably with the EUA Moderna COVID-19 Vaccine to provide the COVID-19 vaccination series.

Moderna COVID-19 Vaccine remains available under EUA:

- As a two-dose primary series for individuals 18 years of age and older,
- As a third primary series dose for individuals 18 years of age and older who have been determined to have certain kinds of immunocompromise, and
- As a single booster dose for individuals 18 years of age and older at least five months after completing a primary series of the vaccine.

Moderna is also authorized for use as a heterologous (or "mix and match") single booster dose for individuals 18 years of age and older following completion of primary vaccination with a different available COVID-19 vaccine. For example, Pfizer-BioNTech COVID-19 Vaccine and Janssen COVID-19 vaccine recipients 18 years of age and older may receive a single booster dose of the Moderna COVID-19 Vaccine.

Spikevax Information

- Package Insert
- Patient Package Insert

Resources

- Letter of Authorization
- Fact Sheet For Healthcare Providers Administering Vaccine
- Fact Sheet for Recipients and Caregivers